

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Joseph L. Duffy, et al.



Serial No. 10/540,283

Filed: June 20, 2005

For: 3-AMINO-4-PHENYLBUTANOIC ACID DERIVATIVES  
AS DIPEPTIDYL PEPTIDASE INHIBITORS FOR THE  
TREATMENT OR PREVENTION OF DIABETES

Art Unit: \_\_\_\_\_

Examiner: \_\_\_\_\_

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK &amp; CO., INC.

By Pamela Spalding Date 8-17-07

**INFORMATION DISCLOSURE STATEMENT**

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

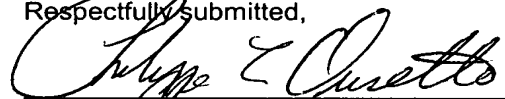
RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☒ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Philippe L. Durette

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 35,125 \_\_\_\_\_

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-4568 \_\_\_\_\_

Date: August 17, 2007 \_\_\_\_\_

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE

## STATEMENT BY APPLICANT

Use as many sheets as necessary)

**1**

of

4

**COMPLETE IF KNOWN**

<b>Application Number</b>	10/540,283
---------------------------	------------

<b>Filing Date</b>	June 20, 2005
--------------------	---------------

<b>First Named Inventor</b>	Joseph L. Duffy, et al.
-----------------------------	-------------------------

## Group Art Unit

Examiner Name

Attorney Docket Number	21304YP
------------------------	---------

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
	1	PCT	WO 97/40832		Hans-Knoll-Institut Fur Naturstoff-Forschung E.V.	11/06/1997
	2	PCT	WO 97/30053		Biomeasure Incorporated	08/21/1997
	3	PCT	WO 98/19998		Novartis AG	05/14/1998
	4	PCT	WO 00/34241		Novartis AG	06/15/2000
	5	PCT	WO 01/34594 A1		Guilford Pharmaceuticals, Inc.	05/17/2001
	6	PCT	WO 01/42262 A2		Akzo Nobel N.V.	06/14/2001
	7	PCT	WO 01/96295 A2		Novartis AG	12/20/2001
	8	PCT	WO 02/02560 A2		Novo Nordisk A/S	01/10/2002
	9	PCT	WO 02/076450 A1		Merck & Co., Inc.	10/03/2002
	10	PCT	WO 03/000180 A2		Merck & Co., Inc.	01/03/2003

Examiner  
Signature

Date  
Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., 06/28/2007

Substitute for form 1449A/PTO <b>INFORMATION DISCLOSURE</b>  <b>STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>COMPLETE IF KNOWN</b>	
				Application Number	10/540,283
				Filing Date	June 20, 2005
				First Named Inventor	Joseph L. Duffy, et al.
				Group Art Unit	
				Examiner Name	
Sheet	2	of	4	Attorney Docket Number	21304YP

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
	11	PCT	WO 03/000181 A2		Merck & Co., Inc.	01/23/2003
	12	PCT	WO 03/004498 A1		Merck & Co., Inc.	01/16/2003
	13	PCT	WO 03/082817 A2		Merck & Co., Inc.	10/09/2003
	14	PCT	WO 2004/007468 A1		Merck & Co., Inc.	01/22/2004
	15	PCT	WO 2004/032836 A2		Merck & Co., Inc.	04/22/2004
	16	PCT	WO 2004/043940 A1		Merck & Co., Inc.	05/27/2004
	17	PCT	WO 2004/050022 A2		Merck & Co., Inc.	06/17/2004
	18	PCT	WO 2004/058266 A1		Merck & Co., Inc.	07/15/2004
	19	PCT	WO 2004/064778 A2		Merck & Co., Inc.	08/05/2004
	20	PCT	WO 2004/069162 A2		Merck & Co., Inc.	08/19/2004

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. Computer generated form "IDS Form" (IDS Folder). Merck & Co., Inc., 06/28/2007

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE**  
**STATEMENT BY APPLICANT**

*(use as many sheets as necessary)*

**COMPLETE IF KNOWN**

<b>Application Number</b>	10/540,283
<b>Filing Date</b>	June 20, 2005
<b>First Named Inventor</b>	Joseph L. Duffy, et al.
Group Art Unit	
Examiner Name	
<b>Attorney Docket Number</b>	21304YP

Sheet	3	of	4
-------	---	----	---

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

Examiner  
Signature

Date  
Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., 06/28/2007

Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE</b>  <b>STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>COMPLETE IF KNOWN</b>	
				Application Number	10/540,283
				Filing Date	June 20, 2005
				First Named Inventor	Joseph L. Duffy, et al.
				Group Art Unit	
				Examiner Name	
Sheet	4	of	4	Attorney Docket Number	21304YP

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	1	Ashworth, D. M. et al., "4-Cyanothiazolidides as very potent, stable inhibitors of dipeptidyl peptidase IV" Bioorganic & Medicinal Chemistry Letters, Vol. 6, No. 22, pp 2745-2748, 1996
	2	Augustyns, K. et al., "Dipeptidyl peptidase IV inhibitors as new therapeutic agents for the treatment of Type 2 diabetes" Expert Opin. Ther. Patents, Vol. 13, No. 4, pp. 499-510, 2003
	3	Deacon, C. F. et al., "Inhibitors of dipeptidyl peptidase IV: a novel approach for the prevention and treatment of Type 2 diabetes?" Expert Opin. Investig. Drugs, Vol. 13, No. 9, pp. 1091-1102, 2004
	4	Deacon, C. F., "Perspectives in Diabetes - Therapeutic Strategies Based on Glucagon-Like Peptide 1" Diabetes, Vol. 53, pp. 2181-2189, 2004
	5	Drucker, D. J., "Therapeutic potential of dipeptidyl peptidase IV inhibitors for the treatment of type 2 diabetes" Expert Opin. Invest. Drugs, Vol. 12, No. 1, pp. 87-100, 2003
	6	Edmondson, S. D. et al., Caplus AN 2003: 42275, P1-4, 2001
	7	Holst, J. J., "Treatment of Type 2 diabetes mellitus with agonists of the GLP-1 receptor or DPP-IV inhibitors" Expert Opin. Emerg. Drugs, Vol. 9, No. 1, pp. 155-166, 2004
	8	Holst, J. J. et al., "Glucagon-like peptide 1 and inhibitors of dipeptidyl peptidase IV in the treatment of type 2 diabetes mellitus" Current Opinion in Pharmacology, Vol. 4, pp. 589-596, 2004
	9	Knudsen, L. B., "Glucagon-like Peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes" J. Med. Chem, Vol. 47, pp. 4128-4134, 2004
	10	Novartis AG: WO0034241 "Novel N-substituted-2-cyanopyrrolidines as potent inhibitors of dipeptidyl peptidase IV in the treatment of non-insulin-dependent diabetes mellitus" Exp. Opin. Ther. Patents, Vol. 10, No. 12, pp. 1937-1942, 2000
	11	Vahl, T. P. et al., "Gut peptides in the treatment of diabetes mellitus" Expert Opin. Investig. Drugs, Vol. 13, No. 3, pp. 177-188, 2004
	12	Weber, A. E., "Dipeptidyl Peptidase IV Inhibitors for the Treatment of Diabetes" J. Med. Chem, Vol. 47, pp. 4135-4141, 2004

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., 06/28/2007